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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,256	09/30/2002	Andrew Kaplan	013341-000014	5660
24239	7590	03/28/2005	EXAMINER	
MOORE & VAN ALLEN PLLC			WOO, JULIAN W	
P.O. BOX 13706			ART UNIT	
Research Triangle Park, NC 27709			PAPER NUMBER	
			3731	
DATE MAILED: 03/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,256

Applicant(s)

KAPLAN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/10/05.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-44, 58, 59, 61 and 73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-57, 60, 62-72 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 61 and 73 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are directed to a neck lift as the cosmetic surgery procedure, which is distinct from the invention originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61 and 73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 45, 46, 60, 62, 63, 72, 77, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Buncke (5,931,855). Buncke discloses, in figures 9-12 and in col. 3, lines 14-44 and col. 7, line 48 to col. 8, line 5; a method of performing a cosmetic surgery procedure or a facelift, where first and second ends of a barbed suture (e.g., 55) are inserted, as claimed, into a point of insertion on the surface of a person's body, where the first and second ends extend out of soft tissue (subepidermal tissue) at exit

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points, where the barbed suture has an elongated body with first and second sharp pointed distal ends or needles (14) and a plurality of barbs (16), as claimed, extending along the periphery of the body, where soft tissue is manually grouped and advanced along the body of the suture (i.e., the suture is tensioned) to provide a desired amount of lift, and where the insertion point of the suture includes a location approximately at the posterior mandibular angle, among other locations (see fig. 12).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 46-54 and 64-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke in view of Coggins et al. (5,217,494). Buncke discloses the invention substantially as claimed, but does not disclose cosmetic procedures including a browlift, a thigh lift, and a breast lift, where the barbed suture is inserted into subepidermal tissues as claimed in order to provide the desired amount of lift in the

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aforementioned body parts. Coggins et al. teach a subepidermal implant and method for lifting loose or sagging tissue in cosmetic surgical procedures (see col. 4, line 51 to col. 5, line 10 for tissues involved in cosmetic surgery), such as a face lift, suspension of the buttock, suspension of the eyelid, a thigh lift, and a breast lift (see col. 2, lines 1-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Coggins et al., to apply the invention of Buncke in cosmetic procedures, such as a browlift (which is actually a type of face lift), a thigh lift, and a breast lift. As in a face lift, Buncke's barbed suture and method, which are analogous to the prosthesis and method of Coggins et al., would also provide an effective means for lifting or suspending other sagging tissues.

6. Claims 55, 56, 74, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke in view of Albright et al. (4,493,323). Buncke disclose the invention substantially as claimed, but does not disclose the application of an insertion device with the suture. Albright et al. teach, in figures 6 and 10-13 and in col. 2, lines 63-68, the application of an insertion device (12) for the insertion of a needle and suture (66) through tissue being joined. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Albright et al., to apply a suture insertion device in the method of Buncke. Such an insertion device would provide a means to insert and guide a needle and suture through tissue at precise locations.

7. Claim 57 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke in view of Albright et al. as applied to claim 55 above, and further in view of

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Coggins et al. Buncke in view of Albright et al. disclose the invention substantially as claimed, but does not disclose a cosmetic procedure that is a brow lift. Coggins et al. teach a prosthesis and method for the lifting of various tissues in cosmetic procedures, including a face lift. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, in view of Coggins et al., to apply the method Buncke in view of Albright et al. to the brow. Such a method would allow the lifting of a precise location as a brow, which is adjacent to tissues commonly lifted in a conventional face lift as disclosed by Buncke and Albright et al.

Response to Amendment

8. With respect to arguments regarding the rejection of claims based on the Buncke reference: The applicant submits that Buncke does not disclose "manually grouping and advancing the soft tissue along at least one portion of the suture to provide a desired amount of lift." On the contrary, Buncke discloses, in col. 3, lines 33-44, that barbs of the suture are engaged "against the internal tissue along the desired lines of tissue support." Moreover, col. 5, lines 5-22 disclose that the skin is said to potentially "pucker," or the skin is "pulled downwardly" by tension in the suture. This action on soft tissue suggests that inherently, tissue is manually grouped and advanced along at least a portion (i.e., the barbed portion) of the suture, when the suture is pulled.

With respect to arguments regarding the rejection of claims based on the references of Buncke and Coggins et al.: Buncke discloses that his device is for cosmetic surgery, including applications in skin wounds, "severed tendons or other internal tissues," "joint capsules," "ligaments," and "subcutaneous layers;" but Buncke

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does not specify the claimed types of cosmetic surgery also taught by Coggins et al. Coggins et al. do indeed teach a tensioned device (a band, which is a type of suture) which has the same principle of operation of Buncke (lifting of tissues with a suture). The design and principle of operation of Buncke is analogous to the device and method of Coggins et al., so Coggins et al. was used as a teaching reference in its combination with Buncke.

Finally, with respect to arguments regarding the rejection of claims based on the references of Buncke and Albright et al.: Buncke et al. disclose a device comprising a needle and a suture. Albright et al. teach, in col. 2, lines 63-68, an insertion device with a tubular element for the delivery of a needle-and-suture combination through tissue. The device and method taught by Albright et al. do not require two needles for delivery of a singular suture through tissue as disclosed by Buncke.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

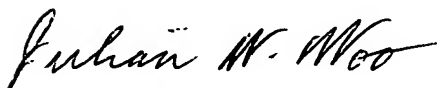
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

March 22, 2005